JUL 3 0 2001

K011532

510(k) SUMMARY FOR PRISM ENTERPRISES, INC.'S MITYVAC® CUPUMP™

Submitter's Name, Address, Telephone Number, And Contact Person

Prism Enterprises, Inc.
6952 Fairgrounds Parkway
San Antonio, Texas 78238-4528

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Prism Enterprises, Inc.
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Date Prepared

May 17, 2001

Name of the Device

Mityvac® CUPumP™

Common or Usual Name

Obstetrical Vacuum Cup

Classification Name

Fetal Vacuum Extractor (21 C.F.F. § 884.4340)

Product Code

HDB

Predicate Devices

The Prism Mityvac® CUPumP™ ("CUPumP") is a modification of the Prism Mityvac® "M" Style™ Vacuum Extractor ("Mityvac M") and the Prism Mityvac® MitySoft® ("MitySoft"). The CuPumP's predicate devices are the Mityvac M, the MitySoft, and Clinical Innovations, Inc.'s Kiwi™ Complete Vacuum ("Kiwi").

Intended Use

The CUPumP, Mityvac M, MitySoft, and Kiwi are to be utilized to assist a clinician in the delivery of an infant during childbirth. All four of these devices are indicated for use during vaginal delivery and Cesarean sections. Thus, the CUPumP has the same intended use and the same indications as its predicate devices.

Technological Characteristics

The primary differences between the CUPumP and the Mityvac M and the MitySoft are: (1) the CUPumP includes a vacuum pump, which is sterile, single use and disposable, while the Mityvac M and MitySoft are labeled for use with Prism's obstetrical vacuum pump; (2) the CUPumP's fetal cup and stem are directly attached to its vacuum pump; (3) one clinician can operate the CUPumP while these predicate devices require two clinicians, one to operate the pump and the other to apply the tractive force on the cup and stem; (4) the CUPumP's operational guidelines state that the reduction of vacuum pressure between contractions is optional while the Mityvac M and MitySoft's labeling recommend that the vacuum pressure be lowered between contractions ; (5) the CUPumP's recommended maximum duration of use is for the total procedure while the Mityvac M's and MitySoft's recommended maximum duration of use is solely pertains to the tractive pressure. The Kiwi, like the CuPumP, includes a sterile, single use, and disposable pump, its fetal cup and stem are directly attached to its obstetrical vacuum pump, and one clinician can operate the device. The instructions for use of the Kiwi state that reduction of vacuum pressure during contractions is optional and the Kiwi does not provide this device's maximum recommended duration of use. Thus, these modifications are not new technological characteristics for fetal vacuum extractors.

Summary Basis for the Finding of Substantial Equivalence

The CUPumP has the same intended use, indications, and very similar technological characteristics and principles of operation as the Mityvac M, MitySoft, and Kiwi devices. Therefore, Prism's Mityvac CUPumP is substantially equivalent to these cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2001

Prism Enterprises, Inc.
c/o Mr. Howard Holstein
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004-1109

Re: K011532
Mityvac CUPumP™ Obstetrical Vacuum
Delivery System
Dated: July 2, 2001
Received: July 2, 2001
Regulatory Class: II
21 CFR §884.4340/Procode: 85 HDB

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K 011532

Device Name: Prism Enterprises, Inc.'s Mityvac® ^{Cu}PumP™

Indications for Use: Prism Enterprises, Inc.'s Mityvac® ^{Cu}PumP™ is intended to be utilized to assist a clinician in the delivery of an infant during childbirth. This device is indicated for use during vaginal delivery and Cesarean sections.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011532